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AND AGENCIES

May 13, 2004

Commissioner of Patents
U.S. Patent and Trademark Office
2011 South Clark Place
Customer Window, **MS Amendment**
Crystal Plaza Two, Lobby, Room 1B03
Arlington, VA 22202

Re: Supplemental Information Disclosure Statement
(Reissue of U.S. 09/571,751, now U.S. 6,479,551)
Appl. No.: 10/811,793
Filed: March 29, 2004
Title: **Treatment of Migraine Headache**
Inventor(s): Plachetka, *et al.*
Atty. Dkt.: 7569/80993

Dear Sir:

The following documents are being forwarded for appropriate action by the U.S. Patent and Trademark Office:

1. Supplemental Information Disclosure Statement;
2. PTO Form-1449, List of References Cited by Applicant;
3. References AH1-AK1, and AL1-AM9; and
4. Return postcard.

Applicants do not believe that any fee is due for the filing of this Information Disclosure Statement. However, the Director is hereby authorized to charge any fee deficiency with respect to this filing and any other fee required in connection with the present case, or credit any overpayment, to our Deposit Account No. 06-1135 under Order No. 7569/80993.

Commissioner for Patents
May 13, 2004
Page 2

It is respectfully requested that the enclosed postcard be stamped with the date the enclosed documents are received by the PTO and that it be returned as soon as possible.

Very truly yours,

FITCH, EVEN, TABIN & FLANNERY

A handwritten signature in black ink, reading "Michael A. Sanzo". The signature is written in a cursive, flowing style.

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Reg. No. 36,912
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MAS:ct
Enclosures



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re reissue patent application of:

Plachetka, *et al.*

Appl. No.: 10/811,793

Filed: March 29, 2004

For: **Treatment of Migraine Headache**

Art Unit: to be assigned

Examiner: to be assigned

Atty. Dkt.: 7569/80993

Supplemental Information Disclosure Statement

Commissioner of Patents
U.S. Patent and Trademark Office
2011 South Clark Place
Customer Window, **MS Amendment**
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Arlington, VA 22202

Sir:

Submitted herewith is a listing of documents known to Applicants and/or their attorney in compliance with the requirements of 37 C.F.R. § 1.56. All of the listed documents are of record in U.S. 6,479,551, the patent for which reissue is now being sought. Copies of the listed documents, except for the U.S. patents, are enclosed.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned attorney submits the following concise explanation of the relevance of the non-English language documents cited on the accompanying form:

Reference A11, European patent document EP 0 774 253, describes compositions for treating migraine headache which contain paracetamol and metaclopramide. An English language abstract corresponding to this document is cited on the accompanying list of references as document AL1.

Reference AJ1, Belgian patent document BE 881 967, describes stable solutions of the alkaloid derivatives of ergot, a process for preparing these solutions, and their use in medicine.

An English translation corresponding to this document is cited on the accompanying list of references as document AM1.

Reference AS1, a scientific article by Becker, *et al.*, describes various pharmacokinetic aspects of a combination of metoclopramide and paracetamol. An English language abstract is included in the article.

Reference AM4, a scientific article by Hoernecke, *et al.*, describes a study in which the treatment of migraine headache with a combination of dihydroergotamine and paracetamol is compared with treatment using the individual agents and with treatment using a placebo. An English language abstract is included in the article.

Reference AR7, a scientific article by Tfelt-Hansen, *et al.*, describes a clinical trial in which migraine patients were treated either with sumatriptan or with the combination of lysine acetylsalicylate and metoclopramide. An English language abstract is included at the end of the article.

Applicants do not waive any rights to appropriate action to establish patentability over any of the listed documents should they be applied as references against the claims of the present application. This statement should not be construed as a representation that more material information does not exist or that an exhaustive search of the relevant art has been made.

Consideration of the cited documents and making the same of record in the prosecution of the above-captioned application are respectfully requested.

Applicants do not believe that any fee is due for the filing of this Information Disclosure Statement. However, the Commissioner is hereby authorized to charge any fee deficiency to our Deposit Account No. 06-1135 under Order No. 7569/80993.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

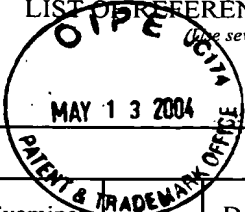
By Michael A. Sanzo

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Attorney for Applicants

Date May 13, 2004
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Phone: (202) 419-7013

<p>LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)</p> 				Atty. Docket No.: 7569/80993		Appl No.: 10/811,793		
				Applicant(s) Plachetka, <i>et al.</i>				
				Filing Date: March 29, 2004		Group: to be assigned		
U.S. PATENT DOCUMENTS								
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate	
	AA 1	2,099,402	Nov. 16, 1937	Keller	167	82	Jan. 17, 1934	
	AB 1	4,024,279	May 17, 1977	Zor, <i>et al.</i>	424	319	Jul. 24, 1975	
	AC 1	4,235,971	Nov. 25, 1980	Howard, <i>et al.</i>	435	293	Jun. 9, 1978	
	AD 1	4,380,540	Apr. 19, 1983	Poyser, <i>et al.</i>	424	233	Jan. 18, 1982	
	AE 1	4,999,226	Mar. 12, 1991	Schock, <i>et al.</i>	424	472	Apr. 27, 1989	
	AF 1	5,037,823	Aug. 6, 1991	Jones, <i>et al.</i>	514	222.8	Dec. 15, 1989	
	AG 1	5,055,306	Oct. 8, 1991	Barry, <i>et al.</i>	424	482	Oct. 20, 1988	
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		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
	AH 1	WO 95/22947	31 August 1995	WIPO	A61F	5/04		
	AI 1	EP 0 774 253	21 May 1997	EPO	A61K	31/165	X	
	AJ 1	BE 881 967	16 June 1980	Belgium	C07D		X	
	AK 1	CA 2,020,018	27 June 1990	Canada	A61K	31/52		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)								
	AL 1	Abstract for AI1 above.						
	AM 1	Translation for AJ1 above.						
	AN 1	STN/CAS online, file EMBASE, Acc. No. 1999161935 (Mandell, <i>Cleveland Clinic Journal of Medicine</i> 66:285-292 (1999), Abstract.						
	AO 1	Albibi, <i>et al.</i> , Metoclopramide: Pharmacology and Clinical Application, " <i>Ann. Int. Med.</i> 98:86-95 (1983).						
	AP 1	Andersson, <i>et al.</i> , "Double-Blind Study of Naproxen vs. Placebo in the Treatment of Acute Migraine Attacks," <i>Cephalalgia</i> 9:29-32 (1989).						
	AQ 1	Bateman, <i>et al.</i> , "Extrapyramidal Reactions to Metoclopramide and Prochlorperazine," <i>Quart. J. Med.</i> 71:307-311 (1989).						
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	AA 2	5,155,105	Oct. 13, 1992	Jones, <i>et al.</i>	514	223.5	Jun. 19, 1991	
	AB 2	5,437,874	Aug. 1, 1995	Bru, <i>et al.</i>	424	466	Jan. 4, 1994	
	AC 2	5,573,776	Nov. 12, 1996	Harrison, <i>et al.</i>	424	435	Sep. 8, 1994	
	AD 2	5,681,583	Oct. 28, 1997	Conte, <i>et al.</i>	424	472	Apr. 25, 1995	
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	AL 2	Boureau, <i>et al.</i> , "Comparison of Subcutaneous Sumatriptan with Usual Acute Treatments for Migraine," <i>Eur. Neurol.</i> 35:264-269 (1995).						
	AM 2	Capobianco, <i>et al.</i> , "An Overview of the Diagnosis and Pharmacologic Treatment of Migraine," <i>Mayo Clin. Proc.</i> 71:1055-1066 (1996).						
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	AO 2	Chabriat, <i>et al.</i> , "Combined Aspirin and Metoclopramide in the Acute Treatment of Migraine Attacks: A Review," <i>Headache Quarterly</i> 8:118-121 (1997).						
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	AQ 2	Cohen, <i>et al.</i> , "Migraine Headache and the Managed Care Formulary," <i>Drug Benefit Trends</i> 8:28-30, 33-34, 41 (1996).						
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	AS 2	Dechant, <i>et al.</i> , "Sumatriptan: A Review of Its Pharmacodynamic and Pharmacokinetic Properties, and Therapeutic Efficacy in the Acute Treatment of Migraine and Cluster Headache," <i>Drugs</i> 43:776-798 (1992).						
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	AL 3	Diamond, <i>et al.</i> , "Do Non-Steroidal Anti-Inflammatory Agents Have a Role in the Treatment of Migraine Headaches?," <i>Drugs</i> 37:755-760 (1989).					
	AM 3	Edmeads, "Four Steps in Managing Migraine," <i>Postgraduate Medicine</i> 85:121-124, 127-128, 131, 132-134 (1989).					
	AN 3	Eldor, <i>et al.</i> , "Ergotamine-Metoclopramide for Migraine: Is It Enough?," <i>Cephalalgia</i> 32:466 (1992).					
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	AP 3	Gamst, "Oral Naproxen Formulations," <i>Scand. J. Gastroenterol.</i> 24:44-47 (1989).					
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	AR 3	Greiff, <i>et al.</i> , "Pharmacokinetic Drug Interactions with Gastrointestinal Motility Modifying Agents," <i>Clin. Pharmacokinetics</i> 27:447-461 (1994).					
	AS 3	Gupta, <i>et al.</i> , "Effect of Metoclopramide on Gastric Ulceration and Secretion in Albino Rats," <i>Arch Int. Pharmacodyn.</i> 297:158-165 (1989).					
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	AL 4	Harrington, <i>et al.</i> , "Metoclopramide: An Updated Review of Its Pharmacological Properties and Clinical Use," <i>Drugs</i> 25:451-494 (1983).					
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	AN 4	Hughes, "Metoclopramide in Migraine Treatment," <i>Med. J. Australia</i> 2:580 (1977).					
	AO 4	Hugues, <i>et al.</i> , "Repeated Doses of Combined Oral Lysine Acetylsalicylate and Metoclopramide in the Acute Treatment of Migraine," <i>Headache</i> 37:454-454 (1997).					
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	AR 4	Kandler, <i>et al.</i> , "Analgesic Action of Metoclopramide in Prosthetic Hip Surgery," <i>Acta. Anaesthesiol. Scand.</i> 37:49-53 (1993).					
	AS 4	Kirby, <i>et al.</i> , "Effect of Metoclopramide, Bethanechol, and Loperamide on Gastric Residence Time, Gastric Emptying, and Mouth-Cecum Transit Time," <i>Pharmacotherapy</i> 9:226-231 (1989).					
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	AL 5	Klapper, "Toward a Standard Drug Formulary for the Treatment of Headache," <i>Headache</i> 35:225-227 (1995).					
	AM 5	Kumar, "Recent Advances in the Acute Management of Migraine and Cluster Headaches," <i>J. Gen. Intern. Med.</i> 9:339-348 (1994).					
	AN 5	Manniche, <i>et al.</i> , "The Pharmacokinetics of the Individual Constituents of an Aspirin-Metoclopramide Combination ('Migravess')," <i>Curr. Med. Res. Opin.</i> 9:153-156 (1984).					
	AO 5	Mathew, "Serotonin 1 _D (5-HT _{1D}) Agonists and Other Agents in Acute Migraine," <i>Advances in Headache</i> 15:61-81 (1997).					
	AP 5	Mohnot, "Treatment of Intractable Headaches," <i>Neurology</i> 36:101 (1986).					
	AQ 5	Ottervanger, "Ketorolac for Severe Migraine," <i>Med. Sci. Bul.</i> 26:49 (1994).					
	AR 5	Peroutka, "Beyond Monotherapy: Rational Polytherapy in Migraine," <i>Headache</i> 38:18-22 (1998).					
	AS 5	Peroutka, "Dopamine and Migraine," <i>Neurology</i> 49:650-656 (1997).					
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	AL 6	Pfaffenrath, <i>et al.</i> , "Analgesics and NSAIDs in the Treatment of the Acute Migraine Attack," <i>Cephalalgia</i> 15:14-20 (1995).					
	AM 6	Pini, <i>et al.</i> , "Disposition of Naproxen after Oral Administration During and Between Migraine Attacks," <i>Headache</i> 33:191-194 (1993).					
	AN 6	Plosker, <i>et al.</i> , "Sumatriptan: A Reappraisal of Its Pharmacology and Therapeutic Efficacy in the Acute Treatment of Migraine and Cluster Headache," <i>Drugs</i> 47:622-651 (1994).					
	AO 6	Pradalier, <i>et al.</i> , "Treatment Review: Non-Steroid Anti-Inflammatory Drugs in the Treatment and Long-Term Prevention of Migraine Attacks," <i>Headache</i> 28:550-557 (1988).					
	AP 6	Pryse-Phillips, <i>et al.</i> , "Guidelines for the Diagnosis and Management of Migraine in Clinical Practice," <i>Can. Med. Assoc. J.</i> 156:1273-1287 (1997).					
	AQ 6	Ross-Lee, <i>et al.</i> , "Single-Dose Pharmacokinetics of Metoclopramide," <i>Eur. J. Clin. Pharmacol.</i> 20:465-471 (1981).					
	AR 6	Ross-Lee, <i>et al.</i> , "Aspirin Pharmacokinetics in Migraine. The Effect of Metoclopramide," <i>Eur. J. Clin. Pharmacol.</i> 24:777-785 (1983).					
	AS 6	Saadah, <i>et al.</i> , "Abortive Migraine Therapy with Oral Naproxen Sodium Plus Metoclopramide Plus Ergotamine Tartrate With Caffeine," <i>Headache</i> 32:95-97 (1992).					
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	AL 7	Scherl, <i>et al.</i> , "Comparison of Dihydroergotamine with Metoclopramide Versus Meperidine with Promethazine in the Treatment of Acute Migraine," <i>Headache</i> 35:256-259 (1995).					
	AM 7	Schwarzberg, "Application of Metoclopramide Specificity in Migraine Attacks Therapy," <i>Headache</i> 34:439-441 (1994).					
	AN 7	Scott, "Dihydroergotamine: A Review of Its Use in the Treatment of Migraine and Other Headaches," <i>Clin. Neuropharmacology</i> 15:289-296 (1992).					
	AO 7	Sevelius, <i>et al.</i> , "Bioavailability of Naproxen Sodium and Its Relationship to Clinical Analgesic Effects," <i>Br. J. Clin. Pharmac.</i> 10:259-263 (1980).					
	AP 7	Silberstein, "Migraine Symptoms: Results of a Survey of Self-Reported Migraineurs," <i>Headache</i> 35:387-396 (1995).					
	AQ 7	Tfelt-Hansen, <i>et al.</i> , "The Effectiveness of Combined Oral Lysine Acetylsalicylate and Metoclopramide Compared with Oral Sumatriptan for Migraine," <i>Lancet</i> 346:923-926 (1995).					
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	AS 7	Tfelt-Hansen, <i>et al.</i> , "Effervescent Metoclopramide and Aspirin (Migravess) Versus Effervescent Aspirin or Placebo for Migraine Attacks: A Double-Blind Study," <i>Cephalalgia</i> 4:107-111 (1984).					
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				Applicant(s) Plachetka, <i>et al.</i>			
				Filing Date: March 29, 2004		Group: to be assigned	
U.S. PATENT DOCUMENTS							
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
FOREIGN PATENT DOCUMENTS							
		Document Number	Date	Country	Class	Subclass	Translation
							Yes No
	AH						
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	AL 9	Wilkinson, <i>et al.</i> , "Migraine and Cluster Headache - Their Management with Sumatriptan: A Critical Review of the Current Clinical Experience," <i>Cephalalgia</i> 15:337-357 (1995).					
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